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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,626	06/05/2001	Johanna Jacoba Maria Meulenberg	4041.1US	9761

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/27/2003

(6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,626	MEULENBERG ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 12, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,10-22 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,10-22,25 and 27-31* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed June 12, 2003 (Paper No. 9) in response to the Office Action of December 12, 2002 is acknowledged and has been entered. Claims 1-4 have been cancelled. Claims 25-31 have been added. Claims 5-7, 10-22 and 25-31 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

New corrected drawings are required in this application, see Notice of Draftsperson review supplied with the last Office Action of December 12, 2002 (Paper No. 7). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

The objection of claim 13 **is withdrawn** in view of applicant's amendment

The objection of claim 10 **is withdrawn** in view of applicant's amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 5-7 and 11-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicant's amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Frolov et al. (PNAS 1996) **is withdrawn** in view of Applicant's amendments.

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Moormann et al. (Journal of Virology 1996) **is withdrawn in** view of Applicant's amendments.

Claim Rejections - 35 USC § 103

Claims 5-7 and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al. (WO 92/21375) in view of Moormann et al. (Journal of Virology 1996) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade, applicant arguments are essentially that there is no motivation to combine the references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally

available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the reference of Wensvoort et al. teaches the nucleic acid sequence of Leystad virus (LV) which belongs to the order *Nidoviralis* (see figure 1). The refences has deposited the virus (CDI-NL-2.91) in the process of isolating the virus the virus was passaged in cells in the petri dish which indicates that the virus was transcribed *in vitro*. The limitation of *in vitro* transcription can be read broadly to include viral production by passaging the virus in a cell culture in a petri dish. Limitation from the specification are not read into the claims. The genome of LV is 14.5 to 15.5 in length (see page 7, lines 15-22). Claim 4 of the Wensvoort et al. reference is drawn to a composition of matter comprising a recombinant vector derived from the LV.

The reference of Moormann et al. teaches *in vitro* transcribing cDNA from a positive stranded RNA virus to produce an infectious clone in the test tube. The reference also teaches replacing the ORF of one virus with the ORF of another strain of virus. Replacing these heterologous nucleic acid sequences produces a virus that can be used as a vaccine, and this vaccine virus can be distinguished from a natural infection by the different antigens it presents. The reference does not teach making an infectious clone of PPRSV.

It remains the position of the office that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cDNA taught by Wenvoort et al. and apply the *in vitro* method taught by Moorman et al. to produce an infectious RNA particle. One of ordinary skill in the art would have been motivated to use an *in vitro* transcribed virus, for the purpose of vaccination because the composition is completely defined. One of ordinary skill in

the art would have been motivated to produce a vaccine that contains heterologous sequences in order to have a marker that can distinguish vaccinated from naturally infected animals. There is a high expectation of success in producing a replication competent virus when exchanging coding sequences from closely related viruses. Therefore, the instant invention is obvious over Wensvoort et al. in view or Moormann et al.

New rejections in view of applicant's amendments to the claims:

Claim Rejections - 35 USC § 102

Claims 25 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wensvoort et al. (WO 92/21375).

The instant invention is drawn to a DNA comprising a full length arterivirus genome Recombinant DNA or recombinant nucleic acid can be interpreted to mean sequences from different sources or manipulating the sequences in any way by well-known laboratory techniques.

Wensvoort et al. teaches the nucleic acid sequence of Leystad virus (LV) which belongs to the order *Nidoviralis* (see figure 1). The references has deposited the virus (CDI-NL-2.91) in the process of isolating the virus the virus was passaged in cells in the petri dish which indicates that the virus was transcribed *in vitro*. The limitation of "*in vitro*" transcription can be read broadly to include viral production by passaging the virus in a cell culture in a petri dish. Limitation from the specification re not read into the claims. The genome of LV is 14.5 to 15.5 in length (see page 7, lines 15-22). Claim 4 of the Wensvoort et al. reference is drawn to a

composition of matter comprising a recombinant vector derived from the LV. Therefore, the instant invention is anticipated by Wensvoort et al

Claims 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Moormann et al. (Journal of Virology 1996).

The instant invention is drawn to recombinant DNA comprising an infectious clone.

Moorman et al. discloses a method of obtaining an infectious RNA virus by *in vitro* translating cDNA. The reference describes the complete cDNA sequence of the C strain (a vaccine strain) of the classical swine fever virus. The reference teaches the construction of a full-length DNA copy of this sequence from which infectious RNA was transcribed. In addition, the infectious copy was used to construct a hybrid virus in which the 5' half of the E2 gene was replaced by the equivalent region from CSFV strain Brescia (see page 768, column 2, 3rd paragraph). Therefore, the present invention is anticipated by Moorman et al.

Claim Rejections - 35 USC § 112

Claims 5-7, 10-12, 14-22, 25, 27-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is broadly claiming RNA viruses that can encompass viruses that are yet undiscovered.

The specification shows the production of a recombinant PPRSV virus, by *in vitro* transcribing RNA from a purified cDNA clone/plasmid, this RNA is then transfected into a cell

that is not a normal host for the virus, the particles are collected selected for by adding to cells that are normally susceptible to the virus.

The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of members of the genus and said function have not been defined. Specifically applicants are claiming the genus of viruses by a process of making the virus (see claims 5, 20, 29-31). In the absence of such a relationship either disclosed in the as filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound would fall within the scope of what is claimed. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was ready for patenting" such as by the use of drawings or structural chemical formulas that show that the invention was complete, or

describing distinguishing identifying characteristics sufficient to show that the applicant was in Possession of the claimed invention.

Claimed invention is drawn to an RNA virus that is made by the process of in vitro transcribing the cDNA and transfecting the transcribed RNA into a non permissive host cell. However, the specification does not provide the sequences of any other virus other than the PPRSV virus. This situation is analogous to that of *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

> *Regents of the University of California v. Eli Lilly & Co., 119* F.3d 559, 1568 (Fed. Cir. 1997), *cert. denied,* 523 U.S. 1089 (1998), the court affirmed a district court ruling that all of the claims of a patent were invalid because the specification did not provide an adequate written description of the rat DNA that was required by the asserted claims. The court said that "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly,* 119 F.3d at 1566 *(quoting Fiers,* 984 F.2d at 1171).
>
> It means little to "invent" a method if one does; not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a cure is illusory, and there is no meaningful possessions of the method. (see 00-CV-6161, March 5th 2003 decision, United States District Court Western District of New York, Judge Larimer).

Because one skilled in the art would conclude that the inventors were not in possession of the full scope of the claimed invention. The claim fails to comply with the written description requirement.

Claim Objections

Claim 26 is objected to because of the following informalities: The claim is dependent on a canceled claim. The claim has not been further treated on the merits. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Before setting out the Double Patenting rejection below a review of the prosecution history in this case 09/874,626 and in the parent case 09/297,535 is necessary. In the parent case 09/297,535 a restriction was made between a virus and a recombinant nucleic acid. Applicants elected the group drawn to recombinant nucleic acids. However, during the prosecution of the parent case 09/297,535 the claimed subject matter changed from the original claimed invention which was drawn to "a recombinant nucleic acid comprising an infectious clone..." and ended up with the patent claims being drawn to "an infectious clone ..." The prosecution of the parent claims clearly indicates that the recombinant nucleic acid and the virus represent a single invention and upon allowance of the claims in the parent application the restriction between the two groups should have been withdrawn. In the instant invention (09/297,535)an election/ restriction was originally made (Paper No. 5) among nucleic acids and a recombinant virus, this restriction was later withdrawn (Paper No. 7) further indicating the groups really represent a single invention.

Claims 5-7 and 10-22 and 25-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,268,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because a species renders the genus obvious. In the instant case the patent claims are drawn to species PPRSV of an infectious RNA virus made by the process of transfecting a non-susceptible host cell with an in vitro transcribed RNA copy of the full length DNA, while the instant claims are broadly drawn to in vitro transcribed RNA of Arteriviridae.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 8/25/03